SEP - 7 2000

K000743

Summary of Safety and Effectiveness **Section 4**

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS
Boston Scientific-Scimed Atlantis™ Coronary Intravascular Ultrasound Imaging Catheter

This Summary of Safety and Effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Applicant Information

Submitter's Name and Address	Boston Scientific SCIMED One Scimed Place Maple Grove, MN 55311
Contact Person	Deborah A. Frank Regulatory Affairs Project Manager (612) 494-2831
Classification:	Class II
Classification Name(s)	Diagnostic Ultrasonic Transducer, 21 CFR Part 892.1570, (90 ITX); and Diagnostic Intravascular Catheter, 21 CFR Part 870.1200, (74 DQO);
Common or Usual Name(s)	Ultrasound Diagnostic Imaging Catheter Diagnostic Ultrasonic Transducer (90 ITX) Diagnostic Intravascular Catheter (74 DQO)
Proprietary Name(s)	Boston Scientific Scimed (BSS) Atlantis™ Intravascular Ultrasound Coronary Imaging Catheter

Summary of Safety and Effectiveness (continued) Section 4

Predicate Device(s)

The Atlantis Coronary Imaging Catheter is substantially equivalent to the following predicate devices:

Product	510(k)	Clearance Date
BSS MicroRail™ 3.2F Coronary Imaging Catheter	K921631	July 2, 1992
BSS MicroView™ 3.2F Coronary Imaging Catheter	K924922	June 29, 1993
BSS Sonicath Ultra™ 3.2F Coronary Imaging Catheter	K970049	June 20, 1997

Device Description

The Atlantis™ coronary intravascular ultrasound imaging catheter consists of two main assemblies:

- Imaging core
- Catheter body

The catheter body is comprised of three sections

- Distal lumen
- Proximal single lumen
- Telescoping section

The distal lumen and proximal single lumen sections comprise the "working length" of the catheter, and the telescoping section remains outside of the guiding catheter. The telescoping shaft (section) allows the imaging core to be advanced and retracted for 15 cm of linear movement. The corresponding movement of the transducer occurs from the proximal end of the wire exit port, to the proximal end of the distal lumen.

The imaging core is composed of a hi-torque flexible, rotating drive cable with an radially looking 40 MHz ultrasonic transducer at the distal tip. An electro-mechanical connector interface at the proximal end makes the connection to the MotorDrive Unit (MDU) / Instrument. The MDU-Catheter interface consists of an integrated mechanical drive hub and electrical connection.

Summary of Safety and Effectiveness (continued) Section 4

Device Description (continued)

A flush port with a one-way valve is used to displace air near the transducer. The catheter must be flushed with heparinized saline prior to use, as this provides the acoustic coupling media required for ultrasonic imaging. The one-way valve helps retain saline in the catheter during use.

The catheter body has a distal guidewire lumen with proximal exit port at approximately 1.5 cm from the distal end. The catheter body is attached to the telescope shaft via a male/female luer connection. A radiopaque (RO) marker is embedded in the catheter body at 0.5 cm from the distal tip. In addition, an insertion depth indicator is located on the catheter body at 105 cm, corresponding to femoral insertions. The catheter is for use with the BSS ClearView Ultra™ System, with High Frequency Option.

Intended Use/Indications

The Atlantis Catheter is intended for ultrasound examination of coronary intravascular pathology ONLY. Intravascular ultrasound imaging is indicated in patients who are candidates for transluminal coronary interventional procedures.

Non-Clinical Test Summary

Performance testing for the Boston Scientific Scimed Atlantis™ Coronary Imaging Catheter demonstrated that the device meets or exceeds the performance requirements for the intended clinical use of the device.

Laboratory (*in vitro)* testing and evaluations were performed on the BSS Atlantis™ Catheter and the results demonstrated that the device satisfies all performance requirements. Biocompatibility testing was conducted in accordance with International Standard ISO-10993, Biological Evaluation of Medical Devices (1995). The results of biocompatibility testing demonstrate that the BSS Atlantis™ Catheter is biocompatible and acceptable for its intended use.

Laboratory testing included acoustic output testing, sheath bond tensile testing, imaging core evaluation and shelf life testing. The testing requirements confirmed that the Atlantis™ Catheter is safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 7 2000

Deborah Frank
Regulatory Affairs Project Manager
Boston Scientific Scimed, Inc.
One Scimed Place
Maple Grove, Mn 55311

Re: K000743
Boston Scientific Scimed ATLANTIS™ Intravascular Ultrasound Coronary Imaging Catheter
Regulatory Class: II (two)
Product Code: DQO
Dated: June 14, 2000
Received: June 15, 2000

Dear Ms. Frank:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic QS inspections, the FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. *Please note*: this response to your premarket notification does not affect any obligation you may have under sections 531 and 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete

information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

If you have any questions regarding the content of this letter, please contact Cindy Demian at (301) 443-8517.

Sincerely yours,

for James E Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosures

Indications For Use — Section 2

510(k) Number:

Device Name: **Boston Scientific Scimed Atlantis™ Coronary Imaging Catheter**

Indications for Use: The Atlantis Coronary Imaging Catheter is intended for ultrasound examination of coronary intravascular pathology ONLY. Intravascular ultrasound imaging is indicated in patients who are candidates for transluminal coronary interventional procedures.

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices
510(k) Number K000743

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use___ OR Over The Counter Use_____
(Per 21 CFR 801.109)